REMARKS

Claim 14 has been amended to recite its dependence on independent claim 11. No new matter has been added. Claims 11, 12, 14, 15, 17-19, 21-23, 25 and 26 are pending.

Rejections under 35 USC § 112

Claims 11, 12, 14, 15, 17-19, 21-23, 25 and 26 were rejected under 35 USC § 112, second paragraph, as being indefinite in the use of the following phrase:

> ... wherein the second hapten or hapten-like molecule is identical to, or an analogue of, the first hapten or hapten-like molecule ...

This phrase appears in paragraph (b) of independent claim 11 and in paragraph (a) of independent claim 19. The Office Action asserts that it is unclear how the first hapten is bound to the analyte specific component but the second hapten is not bound to the analyte specific component, in view of the description of the first and second haptens as being identical to or analogues of each other.

The rejection of the claims under 35 USC § 112, second paragraph is respectfully traversed. Applicants point out that that the interpretation of this phrase in the Office Action is not consistent with the claim language or with the specification. Specifically, the claims do not recite that the first hapten or hapten-

like molecule is bound to the analyte specific component, but rather that the first hapten or hapten-like molecule is linked to the analyte specific component.

The linkage between the first hapten or hapten-like molecule and the analyte specific component is described on page 5, lines 14-18. For example, this linkage or coupling may be a covalent linkage. This is distinct from the reversible binding that occurs between binding pairs, as described on page 4, lines 7-11. Thus, neither the first hapten or hapten-like molecule nor the second hapten or hapten-like molecule bind the analyte specific component. Rather, the only binding that is recited with respect to the first and second haptens or hapten-like molecules is the binding with the binding partner, which is included in the assay component of the claimed method. This is recited in paragraph (c) of claim 11 and in the preamble and paragraph (a) of claim 19.

Applicants respectfully assert that the pending claims are clear and definite when read in light of the actual claim language and when interpreted in light of the use of this language in the specification. Thus, all of the presently presented claims fully meet the requirements of 35 U.S.C. § 112, 2nd paragraph, and Applicants request that this rejection be withdrawn.

Rejection under 35 USC § 102

Claims 11-15, 17-19, 21-23, 25 and 26 were rejected under 35 USC § 102(b) as anticipated by Hevey et al. (U.S. Patent No. 4,228,237). The Office Action asserts that Hevey et al. discloses an assay component bound to a first hapten, and an analyte specific component that specifically binds the ligand to be determined. The Office Action further asserts that Hevey et al. discloses a second hapten identical to the first hapten, in the sense that any excess of the first hapten in the assay will function as a second hapten. The combination and incubation of these components is set forth as providing the method as recited in the claims.

The rejection of the claims under 35 USC § 102(b) is respectfully traversed. Hevey et al. does not disclose, nor has the Office Action asserted that Hevey et al. discloses, each and every element of the claims. Moreover, the correlation of the assay components of Hevey et al. with the components recited in the claims is not consistent with the disclosure of Hevey et al. or with Applicants' specification.

I. Hevey et al. does not teach a homogeneous assay

Independent claims 11 and 19 both recite that the method is directed to a homogeneous assay. Moreover, in the Amendment and Request for Reconsideration filed November 13, 2003, independent claim 11 was amended to recite that the assay mixture is homogeneous, in addition to the recitation of

"homogeneous" as a structural term in the preamble. This amendment was made specifically to insure that the pending claims would be examined in the context of homogeneous assays, since the Advisory Action of September 17, 2003 indicated that the claims had previously been examined in the context of both heterogeneous and homogenous formats.

In contrast, Hevey et al. discloses only heterogeneous sandwich assays. This is clearly stated at the beginning of the "Detailed Description of the Invention" section by the statement "... the present invention may be utilized in any conventional heterogeneous binding process..." (col. 2, lines 33-35; emphasis added). In addition, the general disclosure of assay methods in Hevey et al. consistently recites that the insoluble phase is separated from the rest of the assay after incubation and before any measurements are made, which is descriptive of heterogeneous assays (col. 1, lines 45-50; col. 1, lines 61-66; col. 2, lines 10-15; and col. 2, lines 25-29).

As noted in MPEP § 2131, a reference must teach each and every element of a claim to anticipate the claim. Hevey et al. does not teach, nor has the Office Action asserted that Hevey et al. teaches, a homogeneous assay method. Accordingly, a *prima facie* case of anticipation has not yet been presented. Applicants respectfully request that the rejection of the claims under 35 USC § 102(b) be withdrawn.

II. Hevey et al. does not teach each and every component of the claimed assay

Independent claims 11 and 19 each recite three assay components. As noted in the Amendment and Request for Reconsideration filed April 7, 2003, these ingredients include:

(a) a haptenylated analyte specific component, which includes a 1st hapten or hapten-like molecule linked to an analyte specific component;

(b) a 2nd hapten or hapten-like molecule which is not linked to the analyte specific component; and

(c) an assay component comprising a binding partner which binds to both the 1st hapten or hapten-like molecule (part of ingredient (a)) and the 2nd hapten or hapten-like molecule (ingredient (b)).

In addition to failing to teach a homogeneous assay, Hevey et al. does not disclose each and every ingredient of the method as claimed.

The present Office Action correlates Applicants' ingredient (a) with the "biotin labeled specific binding substance" of Hevey et al., which is listed as reagent (ii) at col. 2, lines 52-53. In this correlation, the biotin is equated with the first hapten or hapten-like molecule, and the specific binding substance is equated with Applicants' analyte specific component. The Office Action further correlates Applicants' ingredient (c) with the "enzyme labeled avidin" of Hevey et al., which is listed as reagent (iii) at col. 2, line 54 and is described as binding to

the biotin (i.e. first hapten) of the biotin labeled specific binding substance. However, even if these two correlations are assumed to be correct, Hevey et al. does not disclose any assay component that can be correlated with Applicants' ingredient (b).

The Office Action has attempted to provide Applicants' ingredient (b) by correlating any excess of the biotin labeled specific binding substance (reagent (ii) of Hevey et al.) with the second hapten or hapten-like molecule recited in the claims. In support of this assertion, the Office Action proposes the following scenario:

> ... biotin (1st hapten) used in excess will saturate binding sites of the specific binding substance (analyte specific component) and the remaining excess biotin (2nd hapten) will bind the avidin (assay component) ... [p. 4, lines 14-16]

Applicants respectfully point out that this scenario incorrectly describes the relationship of the biotin to the specific binding substance as disclosed in the reference. At col. 2, lines 45-53, Hevey et al. discloses that the specific binding substance is labeled with, not bound to, the biotin. The specific binding substance of Hevey et al. binds specifically to the ligand, which is the analyte in that assay (col. 4, lines 31-36). Thus, the biotin does not occupy the binding sites of the specific binding substance, but rather is linked to the specific binding substance in such a way that the specific binding substance is still available to bind the ligand.

Regardless of the scenarios that could be extrapolated from the reference, the relative amount of biotin labeled specific binding substance in Hevey et al. does not change the fact that the biotin is present only as a label on the specific binding substance, and not as an independent hapten. If the biotin of Hevey et al. is correlated with Applicants' first hapten or hapten-like molecule, and if the specific binding substance of Hevey et al. is correlated with Applicants' analyte specific component, then there can be no teaching of Applicants' second hapten or hapten-like molecule that is not linked to the analyte specific component. All of the biotin in the assay of Hevey et al. is present as a label on the specific binding substance, and here is no teaching in Hevey et al. of any biotin that is not linked to the specific binding substance.

Hevey et al. does not teach a second hapten or hapten-like molecule that is not linked to an analyte specific component. As noted in MPEP § 2131, a reference must teach each and every element of a claim to anticipate the claim. Accordingly, a *prima facie* case of anticipation has not yet been presented, and Applicants respectfully request that the rejection of the claims under 35 USC § 102(b) be withdrawn.

CONCLUSIONS

In conclusion, all of the grounds raised for rejecting the application are believed to be overcome or rendered moot based on the remarks above. Thus, it is respectfully submitted that all of the presently presented claims are in form for allowance, and such action is requested in due course. Should the Examiner feel a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned.

Respectfully submitted,

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